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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,188	06/02/2005	Niall Gormley	2713-1-015PCT/US	1232

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,188	GORMLEY ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-3,6-16 and 19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-5 and 17-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/1/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed March 1, 2007. Applicant's arguments have been fully considered. All rejections not reiterated herein are hereby withdrawn. This action is made FINAL.

Claims 1-26 are currently pending. Claims 1-3, 6-16, and 19-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Claims 4 and 17 have been amended. Therefore Claims 4-5 and 17-18 will be addressed herein.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 4 and 17are rejected under 35 U.S.C. 102(b) as being unpatentable over Nazarenko et al (US Patent 6090552 Issued 2000) in view of Cheeseman et al (US Patent 5302509 Issued 1994).

Nazarenko et al teach a hairpin primer which comprises a double stranded stem region, a single stranded loop region, and an additional single stranded region extending from the 3' end of the hairpin which acts as a primer (See Fig 1). In the presence of a target nucleic acid, the target binds to the single stranded region extending from the 3' end of the hairpin. Thus Nazarenko et al teach a single stranded template nucleic acid attached to the 5' end of a hairpin and its complement attached to the 3' end. In the presence of a polymerase and dNTPs the singled stranded region extending from the 3' end of the hairpin is elongated using the target as a template. Nazarenko et al further teach that hairpin nucleic acid has a recognition sequence and a cleavage site and in the presence of a nicking restriction enzyme the elongated strand can be nicked and strand displacement can occur (See Figure 10 and Columns 29-30). Thus the target nucleic acid which is being interpreted as the template nucleic acid is recovered. Additionally the hairpin is being interpreted as a double stranded nucleic anchor because the hairpin probes comprise a double stranded stem region.

Nazarenko et al do not teach a method wherein the sequence of the template nucleic acid is determined as the primer is being extended.

However Cheeseman teach a method for determining the sequence of nucleotides on a template strand of DNA. Specifically Cheeseman teach a single stranded DNA (which acts as a template) hybridized to an oligonucleotide primer. Fluorescently labeled 3'-blocked nucleotide triphosphates, with each of the bases A, G, C, T having a different fluorescent label, are mixed with the bound DNA molecule in the presence of DNA polymerase. The DNA polymerase causes selective addition of only

the complementary labeled NTP, thus identifying the next unpaired base in the unknown DNA strand. The 3'-blocking group is then removed, setting the system up for the next NTP addition and so on. These steps are repeated until the entire target is sequenced (Abstract). Further Cheeseman teach that there are several benefits of sequencing while elongation is taking place. For instance Cheeseman states that (i) the rate limiting step of DNA identification is the rate of a polymerase reaction, (ii) the method is more sensitive therefore smaller quantities of DNA are needed, and (iii) the reagents required for sequencing only require a single mixture of bases rather that four separate preparations (Columns 1-2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Nazarenko et al by determining the nucleic acid sequence of the template nucleic acid as dNTPs are added to the 3' end of the hairpin which acts as a primer as suggested by Cheeseman. A method of sequencing a nucleic acid in a PCR reaction while the elongation step is taking place was routinely used in the art at the time of the invention as demonstrated by Cheeseman et al and thus it would have been obvious to an ordinary artisan to have determined the sequence of the nucleic acid template this way particularly since Cheeseman et al teach that their method has many advantages such as: (i) the rate limiting step of DNA identification is the rate of a polymerase reaction, (ii) the method is more sensitive therefore smaller quantities of DNA are needed, and (iii) the reagents required for sequencing only require a single mixture of bases rather that four separate

preparations. Further it would be obvious that after the template nucleic acid was recovered by the method of Nazarenko that it could be resequenced by the method of Cheeseman for the benefit of verifying the results of the first sequencing reaction.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

3. Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al (US Patent 6090552 Issued 2000) in view of Cheeseman et al (US Patent 5302509 Issued 1994) as applied to claims 4 and 7 above, and in further view of Chernov et al (US 2004/0086866 Filed 10/2002).

The teachings of Nazarenko et al and Cheeseman et al are presented above in paragraph 2.

The combined references do not teach that the hairpin probes are attached to a solid substrate.

However Chernov et al teach the use of hairpin probes attached to a microarray (Para 0013).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of Nazarenko et al and Cheeseman et al by using probes which are attached to a solid substrate as suggested by Chernov et al because it was reported that hairpin probes attached to a chip display higher rates of hybridization and larger equilibrium amounts of captured targets in

comparison with linear probes. Further hairpin-DNA-target complexes are thermodynamically more stable (Para 0013).

Terminal Disclaimer

4. The terminal disclaimer filed on March 1, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No: 10/537186 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

DIANA JOHANNSEN
PRIMARY EXAMINER